

## REMARKS

Claim 1 is amended herein. Claims 2, 3, 12-13, and 15 were previously canceled. Claims 1, 3, 5-11, and 14 are pending and under consideration. The following remarks are in response to the Office Action mailed August 25, 2009 ("the Office Action").

### Interview Summary

Applicants thank Examiner Lichte, who is responsible for this case while Examiner Hoffman is on leave, for the personal interview with their representative, Brenda Jarrell, on October 27, 2009, to discuss the rejection of the claims under 35 U.S.C. § 103. The Examiner indicated that claim 1 would be allowable over the art of record if amended to recite approximate amounts, percentages, or proportions of each of the recited herbals.

### Claim Amendment

Claim 1 has been amended to refer to relative amounts of each of the components of the claimed herbal formula. The amounts are presented as relative percentages based on amounts shown in Table 1 and paragraphs [0074]-[0082] of the specification as originally filed. Thus, for example, percentages of Ling-Zhi are calculated such that when the smallest amount of Ling-Zhi recited in paragraph [0074] is used (15 g), and the largest amount of all other herbals recited in paragraphs [0075]-[0081] are used in a batch preparation (232 g), the smallest percentage of Ling-Zhi in an herbal mixture is  $15 \div 247 = 6\%$ . Likewise, if the largest amount of Ling-Zhi recited in paragraph [0074] is used (80 g), and the smallest amount of all other herbals recited in paragraphs [0075]-[0081] are used in a batch preparation (73.5 g), then it follows that the largest percentage of Ling-Zhi in an herbal mixture is  $80 \div 153.5 = 52\%$ . Paragraph [0082] provides that in certain embodiments, it is desirable to preserve ratios of herbal components.

The table below details the percentage calculations for all of the recited herbals. For clarity, Applicants specifically require that the percentages of all of the recited herbals equal 100%.

<b>Herbal</b>	<b>Lowest amt</b>	<b>Highest amt</b>	<b>Lowest percentage</b>	<b>Highest percentage</b>
Ling-Zhi	15 g	80 g	$15/247 = 6\%$	$80/153.5 = 52\%$
Wu Mei	30 g	80 g	$30/262 = 11\%$	$80/138.5 = 58\%$
Chuan Jiao	1.5 g	3 g	$1.5/310.5 = 0.5\%$	$3/90 = 3\%$
Huang Lian	9 g	15 g	$9/306 = 3\%$	$15/94.5 = 16\%$
Huang Bai	6 g	80 g	$6/238 = 2.5\%$	$80/162.5 = 49\%$
Gan Jiang	6 g	15 g	$6/303 = 2\%$	$15/97.5 = 15\%$
Gui Zhi	3 g	9 g	$3/306 = 1\%$	$9/94.5 = 9.5\%$
Ren Shen	9 g	15 g	$9/306 = 3\%$	$15/94.5 = 16\%$
Dang Gui	9 g	15 g	$9/306 = 3\%$	$15/94.5 = 16\%$

Applicants respectfully submit that no new matter is added by the amendment to claim 1.

Rejections under 35 U.S.C. § 103

Claims 1, 3, 5-8, 10, 11, and 14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sampson (WO 01/66122; “Sampson”). Claims 8 and 9 were rejected over Sampson in further view of the specification.

Applicants respectfully disagree with the rejections for reasons detailed in the previous response to non-final office action. However, in order to expedite prosecution, Applicants have amended claim 1 to recite relative percentages of components in the claimed herbal formula of claim 1. Sampson does not disclose or suggest an herbal formula for treating or lessening the severity of food allergy, wherein the formula comprises an herbal mixture consisting of the recited nine components at the specified percentage ranges.

Applicants previously noted that one would not have expected efficacy of compositions lacking certain components shown to be effective in Sampson. In support of this, Applicants submitted Kattan et al. (*Phytother. Res.*, 22:651-659, 2008) to show that simplified herbal preparations lacking components can be far less effective than a more complex formulation. In the Office Action, the Examiner responded to Applicants’ arguments and submission by stating (page 3, carryover paragraph to page 4):

this evidence of unexpected results is not considered to render the claimed invention patentable over the prior art because the unexpected results are not commensurate in scope with the claimed invention (see MPEP 716.02(d)). Table 1 in applicant's specification describes the ingredients in FAHF-2...*Applicant's current claims are not limited to a particular amount* of each ingredient. Thus, applicant's showing of unexpected results is not commensurate in scope with the claimed invention. Therefore, the claims are not considered to be allowable based on unexpected results (emphasis added).

Applicants note that the claims, as amended, refer to relative amounts based on amounts provided in Table 1 of the specification. The relative amounts of each component shown in Kattan et al., Table 2, fall within the relative amounts of each component in the claims. Claim 1, as amended, thus provides features suggested by the Examiner as commensurate in scope with results acknowledged to be unexpected. Claims 3, 5-11 and 14 depend from claim 1 or include all of its limitations.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1, 3, 5-8, 10, 11, and 14 as unpatentable over Sampson.

### Conclusion

Applicants invite the Examiner to contact the undersigned, Margo H. Furman, at (617) 248-4073 with any questions pertaining to the above-identified application in order to expedite prosecution of this case. This Response is being filed with a Petition for Extension of Time and required fee. In the event that any further extensions or fees are required, please consider this a conditional petition and authorization to charge any fees to Deposit Account No. 03-1721, referencing attorney docket no. 2005577-0010.

Respectfully submitted,

Dated: January 22, 2010

/Margo H. Furman/  
Margo H. Furman, PhD  
Reg. No. 59,812

PATENT GROUP  
CHOATE, HALL & STEWART  
Two International Place  
Boston, MA 02110  
Tel: (617) 248-5000  
Fax: (617) 502-5002  
patentdocket@choate.com